510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

MAY 2 4 2006

1. GENERAL INFORMATION

Trade Name	BIO 1-KIT ® BIOSORB® filled cartridge
Common Name	Bone void filler and bone graft delivery syringe
Classification Name	Resorbable Calcium Salt Bone Void Filler device
Class	II
Product Code	MQV
CFR section	21CFR 888.3045
Device panel	Orthopedic
Legally marketed predicate devices	BIOSORB® Resorbable Void Filler K021963 (SBM) VITOSS-Filled cartridge K032130 (Orthovita Inc)
Submitter	SCIENCE FOR BIOMATERIALS Sciences et Bio Matériaux ZI du Monge F 65100 LOURDES – FRANCE Owner operation Number : 9063735 Establishment Registration Number:3004549189
Contact	Denis CLEMENT, General Manager Phone : +33 (0)5 62 42 21 01 Fax : +33 (0)5 62 42 21 00 e-mail : denis.clement@sbm-fr.com Regulatory contact: Idée Consulting (FRANCE) Isabelle DRUBAIX e-mail : idrubaix@nordnet.fr

2. DEVICE DESCRIPTION

BIOSORB ® bone void filler (BIO1 range of products) (K021963) is an osseo-conductive macroporous implant made of synthetic beta tri Calcium Phosphate (βTCP) indicated for Bone Void Filling.

BIOSORB ® bone void filler presents a multidirectional interconnected porosity structure (45% and 70%), similar to that of the human cancellous bone. BIOSORB ® bone void filler implant slowly resorbs during the remodeling and bone defect repair process and is progressively replaced with bone and soft tissues. The progressive resorption within 6–12 months prevents premature resorption and failed filling.

The impregnation of bone substitute with marrow is largely practiced by the surgeons. Usually this operation is done by immersion of the bone substitute in a container containing the osseous marrow. In order to facilitate this operation and to limit the contact of the mixture with the ambient air at the origin of the degradation of the cells

and proteins contained in osseous marrow, S.B.M has developed a system allowing the puncture of autologous osseous marrow, the impregnation of the calcium phosphate pellets and the impaction of the mixture in the cavity to be filled. This system allows the impregnation of porous pellets with osseous marrow under aseptic conditions.

BIO 1-Kit® comprises :

- a pre-filled syringe of BIOSORB® (β-TCP porous ceramic pellets)
- a connector with an adapter and a needle
- a bone marrow aspiration needle

BIO 1-Kit® is delivered sterile and intended for a single use.

BIO 1-Kit® is available either with BIOSORB® granules (1.5 and 3.0 mm in diameter) or BIOSORB® blocks (4x4x4 mm) and in quantities ranging from 5 cc to 45 cc.

3. INTENDED USE

BIOSORB ® Resorbable Void Filler is a resorbable calcium salt bone void filler intended to fill bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis,) caused by trauma or surgery, that are not intrinsic to the stability of the bony structure.

BIOSORB ® Resorbable Void Filler does not possess sufficient mechanical strength to support reduction of a defect prior to soft and hard tissue ingrowth. Rigid fixation techniques are recommended as needed to assure stabilization of the defect in all plans.

The BIO 1-KIT ® BIOSORB® filled cartridge is intended for use as a piston syringe system for the aspiration of autogenous blood and/or bone marrow. This cartridge provides the surgeon with a convenient way to mix autologous blood or bone marrow with the BIOSORB ® Resorbable Void Filler and deliver the material to the orthopedic surgical site.

4. PERFORMANCE DATA

BIOSORB® (K021963) conforms to the recognized consensus standard specification ASTM F 1088-2004 Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation. FDA has recognized the use of this consensus standard as verification of material characteristics and biocompatibility for surgical application (Recognition List Number: 011 Effective Date: 09/01/2004).

Moreover, the biocompatibility of βTCP implants is well documented. As a biomaterial β TCP has consistently proven to be non toxic, non allergenic, biocompatible and elicits no inflammation. No adverse system effects have been reported.

A wide variety of tests (cytotoxicity, sensitization, genotoxicity and mutagenicity, systemic toxicity, irritation, systemic tolerance, Pyrogenicity) was performed on

K061022

BIOSORB® (refer to K021963). Testing performed on BIOSORB® shows an excellent biocompatibility with no significant adverse observations of any kind.

A human clinical trial (K021963) has been performed to investigate the safety and effectiveness of BIOSORB ® bone void filler and more especially the achievement of a stable osseous fusion in consolidation of bone defects, the absence of inflammatory or septic response and the resorption of the BIOSORB ® implant and its replacement by osseous tissues. Clinical and radiological data demonstrate the biocompatibility, the osseo integration and the resorption of BIOSORB ® bone void filler.

In addition the following tests were performed on the BIO 1-KIT ® BIOSORB® filled cartridge:

- The compatibility and the absence of particles release from the polypropylene syringe has been assessed by infra-red spectrometry
- Testing of aspiration and impregnation has been performed

5. SUBSTANTIAL EQUIVALENCE

BIO 1-KIT ® BIOSORB® filled cartridge is substantially equivalent to its predicate device VITOSS-Filled cartridge K032130 (Orthovita Inc) in terms of intended use, material, design and function. Any minor differences between these two devices do not raise new questions of safety and effectiveness.

Summary preparation date: March 31, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2006

Science for Bio Materials
% Mr. Denis Clement
General Manager
ZI du Monge
F 65100 Lourdes – France

Re: K061022
Trade/Device Name: BIO 1-KIT® BIOSORB® filled cartridge
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: April 7, 2006
Received: April 24, 2006

Dear Mr. Clement:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

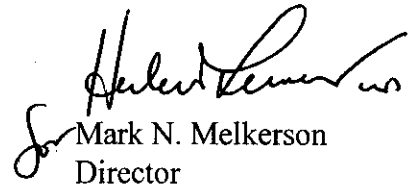
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

Indications For Use:

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

cc: HFZ-401 DMC

510(k) Number (if known): K061022

Device Name: BIO 1-KIT ® BIOSORB® filled cartridge

Indications for Use:

BIOSORB ® Resorbable Void Filler is a resorbable calcium salt bone void filler intended to fill bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis,) caused by trauma or surgery, that are not intrinsic to the stability of the bony structure.

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061022 000002